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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,038	07/11/2003	Peter Andersen	SSI5AUSA	5215
270	7590	10/26/2005	EXAMINER	
HOWSON AND HOWSON ONE SPRING HOUSE CORPORATION CENTER BOX 457 321 NORRISTOWN ROAD SPRING HOUSE, PA 19477			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,038

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-17 is/are rejected.
- 7) ☒ Claim(s) 10 and 13 is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7-11-03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/03, 11/03, 1/04, 2/</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 11 August 2005, is acknowledged. Applicants elect, with traverse, Invention IV, claims 6-10, 12, 13, 16, and 17, drawn to polypeptide compositions, classified in class 424, subclass 248.1.

Applicant's traversal is on the grounds that the provisionally elected group should also encompass embodiments in which the polypeptide vaccine compositions further contain a nucleic acid molecule.

The examiner has reconsidered the Restriction Requirement in light of applicants' arguments. Claims 11, 14, and 15 will be rejoined with claims 6-10, 12, 13, 16, and 17 as being drawn to vaccine compositions.

However, claims 1-5 and 18-22, drawn to methods of immunization and diagnosis, remain under the Restriction Requirement for the reasoning put forth in the original Office Action.

Claims 1-22 are pending. Claims 1-5 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 6-17 are under consideration.

Drawings

3. Figures 6A and 6B are objected to because of a difference in depiction of the letter g compared to the other figures. It is recommended that the same font be used in all figures in the depiction of IFNg and pg.

Priority Statement

4. The priority statement at the beginning of the specification should be amended to cite the priority claim to the foreign document.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (page 42, line 3 and 6). See MPEP § 608.01.

6. The disclosure is objected to because of the following informalities:

Page 1, line 7, delete the period after "*tuberculosis*",

Page 3, lines 7 and 31, refer to reference "Turner, 2000" which is not in the reference list on pages 63-65,

Page 33, paragraphs 5 and 6 are identical,

Page 39, line 30, what is the reference for "Merrifield"?,

Page 43, line 21, what is meant by "><",

Page 55, the last paragraph should not be italicized; last line, "table" should be "Table",

Page 56, line 1, "Prim r" should be "Primer",

Page 58, line 4 of paragraph, "M. tuberculosis" should be "*M. tuberculosis*",

Page 59, line 17, "E. coli" should be "*E. coli*",

Page 63, line 25, "M. tuberculosis" should be "*M. tuberculosis*",

Appropriate correction is required.

Claim Objections

7. Claim 10 is objected to because of the following informalities: line 2, "partners is" should be "partners are" or "partner is". Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: line 2, "components"...."comprises" should be "component" "comprises" or "components" "comprise".

Appropriate correction is required.

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9.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "polypeptides upregulated during the latent stage" in the claim.

Claim 7 recited "vaccine according to claim 6 where the polypeptides upregulated during the latent stage of the mycobacteria infection". Claim 6 does not recite that the polypeptides are "upregulated during the latent stage", but "polypeptides are expressed during the latent stage". Thus, there is a lack of antecedent basis in claim 7 for "polypeptides upregulated during the latent stage". Claim 8 depends from claim 7, but does not correct the insufficiency.

12. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to a vaccine wherein the polypeptides of claim 6 are fused to other "antigens" expressed by bacteria within the mycobacteria family. Claim 10 depends from claim 9 and recites "where the fusion partners is". It is unclear if the construct of claim 9 is a polypeptide/fragment thereof with only one or multiple "other antigens". Claim 10 compounds the indefiniteness by reciting "partners is".

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13. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is drawn to a multiphase vaccine comprising antigen "components" with therapeutic activity combined with antigen "components" with prophylactic activity. Claim 13 depends from claim 12 and recites "where the antigen components with prophylactic activity comprises". It is unclear how many "components" are combined in the construct of claim 12, e.g., one therapeutic with one prophylactic, or some other number. Claim 13 compounds the indefiniteness by reciting "components.....comprises".

14. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "the effective component a non-pathogenic microorganism" in the claim.

Claim 14 recited "A vaccine according to claim 6, comprising as the effective component a non-pathogenic microorganism". Claim 6 does not recite either "effective component" nor a "microorganism". Claim 15 depends from claim 14, but does not correct the insufficiency.

In addition, claims 14 and 15 improperly depend from claim 6 by expanding the scope of the claims. Claim 6 is drawn to a vaccine comprising one or more polypeptides. The claim does not recite that the vaccine also comprises a microorganism.

15. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "the antigen components" in the claim.

Claim 16 depends from claim 6. Claim 6 does not recite "antigen components".

16. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "the amino acid sequence" in the claim.

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Claim 17 depends from claim 6. Claim 6 does not recite "amino acid sequence".

17. Claims 6-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccine against tuberculosis comprising polypeptides, does not reasonably provide enablement for vaccines comprising merely the nucleic acids encoding these polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – A therapeutic vaccine against tuberculosis comprising one or more nucleic acids encoding polypeptides expressed during the latent stage of the mycobacteria infection.

The state of the prior art concerning therapeutic vaccines against tuberculosis wherein said vaccines comprise merely nucleic acids indicates a lack of predictability concerning successful vaccination (Wang et al, *Expert Rev. Vaccines*, 1(3):341-354, 2002).

The amount of direction/guidance/examples present in the instant specification is insufficient to support the broad scope of the instant claims. While the specification may

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speculate on such nucleic acid vaccines, the specification only provides examples of polypeptide vaccines.

Therefore, the quantity of experimentation necessary to support the scope of the instant claims, i.e, nucleic acid vaccines, appears to constitute merely an invitation to experiment without a reasonable expectation of success.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenberg et al (WO01/35317, 17 May 2001).

An embodiment of the claims is a therapeutic vaccine comprising a whole polypeptide or an immunogenic fragment of one polypeptide identified by SEQ ID NO:4.

Eisenberg et al teach the invention (SEQ ID NO:165, page 158).

Conclusion

20. No claims are allowed.

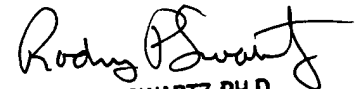
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

October 21, 2005